

## **Section II (Remarks)**

### **Regarding the Amendments**

Claims 1, 4, 30, 32, 37, 47, 54, 55, 57 and 58 have been amended, claim 59 has been cancelled, and new claim 61 has been added as set forth in the Complete Listing of the Claims. As amended, the claims are supported by the specification and original claims.

Specifically, the amendments to claims 1 and 30 are supported by paragraphs [0064] – [0068] of the original specification. The amendments to claims 4, 32, 37, 47, 54, 55, 57 and 58 are supported by the current or previously presented version of each respective claim. The amendment to claim 54 is supported by paragraphs [0032] – [0035] of the original specification. The addition of claim 61 is supported by the currently pending claims 32 and 37.

No new matter has been added, as defined by 35 U.S.C. §132(a). By the present amendment, cancellation of claim 59 is requested, without prejudice.

Thus, upon entry of the amendments, claims 1, 2, 4, 6, 7, 9, 30, 32, 34, 35, 37-42, 47-55, 57-58, 60 and 61 will be pending under examination.

### **Rejection of Claims Under 35 U.S.C. § 103**

In the Office Action dated August 4, 2009, the Examiner raised an objection to the patentability of the subject matters of pending claims 1, 2, 4, 6, 7, 9, 30, 32, 34, 35, 37-42, and 47-60 under 35 U.S.C. § 103(a) over the newly cited U.S. Patent No. 6,072,396 (hereinafter “Gaukel”) in view of U.S. Patent Publication No. 2004/0073093 (hereinafter “Hattestad”).

It is elemental law that in order for an invention to be obvious, the difference between the subject matter of the application and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. In order to meet this standard for a proper §103 rejection, all claim limitations must be disclosed or derivable from the cited combination of references, there must be a logical reason to combine the cited references to produce an operable combination and there must be a reasonable expectation of success. (MPEP § 2143.03)

Gaukel in view of Hatlestad fail to provide any derivative basis for the claimed invention. Accordingly, no basis of prima facie obviousness of the claimed invention is presented by such cited references.

Applicant submits that the claimed invention as set forth in the newly amended claims is not obvious over Gaukel in view of Hatlestad. As amended, independent claims 1 and 30 now recite that “the second predetermined physiological parameter threshold value is calculated using equation of  $T = \mu + k\sigma$ , wherein  $T$  represents the second predetermined physiological parameter threshold value,  $\mu$  represents the mean value of a predetermined number of readings of the physiological parameter,  $k$  represents a positive number up to 3, and  $\sigma$  represents the standard deviation of the predetermined number of readings of the physiological parameter.” This feature is neither disclosed nor suggested in the cited prior art, including Gaukel or Hatlestad. Moreover, there is no motivation for a skilled person in the art to arrive at such feature.

Support for such amendment is found, for example, in paragraphs [0064] – [0068] of the present application, where  $k$  is defined as a positive number, and in the example given in paragraph [0065],  $k$  is set to be 3 in keeping with the original disclosure that allows  $k$  to be a positive number up to 3.

In this context, using the above equation for determining whether the person has a physical condition has the advantage that it takes into account the natural fluctuations of body temperature of an individual as distinguished among other individuals, thereby reducing the possibility of a false indication of physical condition. The natural variation of the body temperature of an individual is modeled to be a normal distribution. By setting  $k$  to be a positive number up to 3, the confidence level of the indication of a physical condition can be adjusted.

With respect to independent claim 1, the August 4, 2009 Office Action concedes that Gaukel fails to disclose correction factors to the measured signals.<sup>1</sup>

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<sup>1</sup> See August 4, 2009 Office Action, pages 3-4.

In seeking to remedy this deficiency in Gaukel's disclosure, the Office Action alleges that Hatlestad discloses a physiological monitoring system that applies correction factors to compensate for the context, and that the combination of Gaukel with the correction factors of Hatlestad would have been obvious to one of ordinary skill in the art.<sup>2</sup>

While Hatlestad does disclose "flag[ing] data as being recorded during an appropriate patient context so that the data is acceptable"<sup>3</sup>, this disclosure is in the context of a pulse rate taken during a particular physiological situation, such as lying down, standing up, or running, where each pulse rate for the specific physiological situation varies widely enough that different contexts are required.<sup>4</sup> Thus, Hatlestad contemplates different contexts among a **single individual**, while claim 1 focuses on the physiological parameters that **differentiate the physiological parameters of one individual among those of other individuals** in utilizing the equation of  $T = \mu + k\sigma$ , wherein  $T$  represents the second predetermined physiological parameter threshold value,  $\mu$  represents the mean value of a predetermined number of readings of the physiological parameter,  $k$  represents a positive number up to 3, and  $\sigma$  represents the standard deviation of the predetermined number of readings of the physiological parameter. Accordingly, the subject matter of amended claim 1 is inventive and patentable over the prior art.

Likewise, and for the same reasons, the equation of  $T = \mu + k\sigma$ , wherein  $T$  represents the second predetermined physiological parameter threshold value,  $\mu$  represents the mean value of a predetermined number of readings of the physiological parameter,  $k$  represents a positive number up to 3, and  $\sigma$  represents the standard deviation of the predetermined number of readings of the physiological parameter distinguishes the subject matter of amended claim 30, and such subject matter is inventive and patentable over the prior art.

The same argument would apply for the amendments made to claim 47 of the application as made herein. As previously discussed, Hatlestad distinguishes various contexts among different physiological situations **within a single individual**. Claim 47, however, specifically "compare[s] the physiological parameter reading with a second predetermined physiological parameter threshold value to determine if the person has a physical condition, wherein the

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<sup>2</sup> *Id.*, at 4.

<sup>3</sup> See Hatlestad, para. [0027].

<sup>4</sup> *Id.*, at [0023]-[0025], and [0026].

physiological parameter is body temperature.” Here, the comparison of claim 47 distinguishes the parameters **among those of other individuals**. Therefore, Hatlestad fails to remedy the deficiencies of Gaukel in disclosing the features of Applicant’s amended claims 1, 30 and 47.

Claim 54 has been amended herein in response to the rejections presented in the August 4, 2009 Office Action. The amendment to claim 54 is supported by paragraphs [0032] – [0035] of the original specification. Neither Gaukel nor Hatlestad discloses a system containing the particular features of claim 54, wherein the at least one physiological parameter measuring device comprises: a transducer; a transmitter; and a processor connected to the transducer and the transmitter, said physiological parameter measuring device further comprising a housing including: a first portion; a second portion; and a flexible medial portion connected between the first and the second portion, wherein the processor, transmitter and receiver are accommodated within the first housing portion and the transducer is supported on the second housing portion.

Based on the failure of Gaukel to disclose elements conceded by the examiner to be absent from Hatlestad, withdrawal of the rejection of independent claims 1, 30 and 47 under 35 U.S.C. § 103 is warranted, and is respectfully requested. Likewise, neither Gaukel nor Hatlestad discloses the particular features as recited in amended claim 54, and thus withdrawal of the rejection of independent claim 54 under 35 U.S.C. § 103 is also warranted, and is respectfully requested. Because dependent claims inherently include all of the features of the claims on which they depend<sup>5</sup>, the claims depending (whether directly or indirectly) from claims 1, 30, 47 and 54 are likewise distinguished over the cited art. Withdrawal of the rejections of all claims depending from claim 1 is correspondingly warranted, and such action is respectfully requested.

### CONCLUSION

The time for responding to the August 4, 2009 Office Action without extension was set at three months, or November 4, 2009. With one new dependent claim 61 added and one dependent claim 59 cancelled, there are no changes in the total number of claims. Therefore, with this Response being timely filed and no change in the number of claims, no fees are believed to be

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<sup>5</sup> 35 U.S.C. 112, fourth paragraph.

due for the filing of this paper. Should any fees be required, however, please debit our Deposit Account No. 08-3284, as necessary.

Based on the foregoing, all of Applicants' pending claims 1, 2, 4, 6, 7, 9, 30, 32, 34, 35, 37-42, 47-55, 57-58, 60 and 61 are patentably distinguished over the art, and in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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